UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,179	03/12/2004	Manoj Kumar	DOC0057PA/DC5074/GC792-4	8989

7590 05/17/2006

DINSMORE & SHOHL LLP
One Dayton Centre
Suite 500
One South Main Street
Dayton, OH 45402-2023

EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,179	KUMAR ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *5-7,10,11,16-30,32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,9,12-15 and 31* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Withdrawal of Finality / Status of Claims

The finality of the Office action mailed July 21, 2005 is withdrawn, in view of the rejections set forth below.

Further, the indication that the subject matter of claim 19 is withdrawn in view of the Double Patenting rejections below.

Claims 1-33 are pending and **claims 5-7, 10, 11, 16-30, 32 and 33** remain withdrawn for the reasons of record. **Claims 1-4, 8, 9, 12-15 and 31** have been examined on the merits.

Response to Arguments

Applicant's arguments filed February 21, 2006 (Appeal Brief) are acknowledged and have been considered. Applicant's arguments have been found persuasive to the extent that the Examiner erroneously applied the structure of Type I collagen to a Type V collagen.

Applicant further argues that the sequence of collagen in Voet does not meet the limitations of the instant claims. This has not been found persuasive, as the structure template recited in claims 1 and 3 are not limiting in what is, or is not, embraced by the formula, as addressed below. Applicant asserts that the there is a requisite 30 amino acid minimum in the peptide (page 8), and implies throughout the arguments that the units A, A′ and A′′ each have at minimum 3 amino acids, while the claim clearly recites "about 3 to about 30", where a reasonable interpretation for "about 3" is 1 amino acid. "About 3" is of a vastly broader scope than a recitation of "3 amino acids" or "a tripeptide".

New Grounds of Rejection/Objection

Claims 1 and 3 are objected to for because they recite "T and T′ each comprise an amino acid sequence of from about 1 to about 100 amino acids", however 1 amino acid is not a sequence of amino acids. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8, 9, 12-15 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of

such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus (MPEP § 2163). If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus (MPEP § 2163). Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. While all of the factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to personal care compositions that is "adapted to provide at least one benefit to the surface" to which it is applied, comprising an effective amount of a repeat sequence protein polymer (RSPP) of the formula (emphasis added by the examiner):

$T_y[(A_n)_x(B)_b(A'_{n'})_{x'}(B')_{b'}(A''_{n''})_{x''}]_iT'_{y'}$.

T and T′ are present or absent (y and y′= 0 or 1) and each comprise an amino acid sequence of about 1 to about 100 amino acids

A, A′, A′′ are present or absent (x, x′ and x′′ = 0 or 1) and each comprises about 3 to about 30 amino acids and each is repeated 2 to 250 times (n, n′ and n′′=2 to 250).

B and B′ are about 4 to about 50 amino acids and repeated 0 to 3 times (b and b′= 0 to 3).

The peptide bounded by T and T′ is present once or repeated up to 100 times (i = 1 to 100).

"Personal care composition refers to a product for application to the skin, hair, nails, oral cavity and related membranes for the purposes of improving, cleaning, beautifying, therapeutically treating, caring for these surfaces and membranes" (paragraph [0015]).

"An effective amount refers to the amount of [an RSPP] which is added to a personal care composition to provide the composition with a desired characteristic or characteristics." (paragraph [0016]).

(1) Level of skill and knowledge in the art:

The synthesis of peptides is well known in the art, however the synthesis of an infinite number of peptides with any of a myriad of "desired characteristic(s)" and compositions which are used in a myriad of functions embraced by the claims is beyond that the skill of the artisan, particularly since the intended use (e.g. application to the hair for cleaning, or application to the

skin for improving the surface, etc.) and the 'desired characteristics' are undefined or unable to be correlated with a particular structure.

(2) Partial structure:

The claims recite the structure above and that the RSPP can comprise, e.g. collagen, elastin, etc. (claim 2), however each variable is limitless, as A, A′, A′′ each comprises about 3 to about 30 amino acids, and thus does not set boundaries on the units.

Furthermore, Applicant's arguments assert that it is clear that minimum peptide length must be at least 30 (page 4, 1st paragraph), while the claim infers that it must be at least 90 (x, x′ and x′′ are varied "to provide for at least 30 amino acids in the A, A′, A′′ individual repeating sequence units" (e.g. claim 1). One interpretation is that each has at least 30 amino acids (30 + 30 + 30 = 90).

The specification provides examples of repeating sequence units and the sources of some repeat units, however the specification does not provide a sufficient number of species to describe the whole genus with the 'desired characteristic(s)' .

(3) Physical and/or chemical properties and (4) Functional characteristics:

The composition must comprise a peptide embraced by the genus and the composition must be "adapted to provide at least one benefit to the surface", where the benefit desired and the surface are both undefined.

(5) Method of making the claimed invention:

The specification provides the source of some individual repeating sequence units and provides methods of making peptides and compositions, however the specification fails to adequately describe which compounds are to be made to obtain the specific desired result.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 1 is a broad generic, with respect to all possible compounds encompassed by the claims, and the compositions comprising them. The possible structural variations are limitless to any class of peptide comprising 'personal care composition'.

It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus, as the few examples in the specification are insufficient to describe all of the peptide compositions embraced by the claims with any of an infinite number of benefits.

While having written description of compositions comprising SEQ ID NO:19 and the various SELPs identified in the specification tables and/or examples, the specification is void of a sufficient number of examples to describe the infinite number of peptide compositions within the genus with the requisite activity.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the

specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8, 9, 12-15 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 3 are unclear and indefinite, as they recite that A, A′ and A′′ are "each individual repeating sequence units comprising from about 3 to about 30 amino acids", and further in the claims x, x′ and x′′ are varied "to provide for at least 30 amino acids in the A, A′ and A′′ individual repeating sequence units". One limitation indicates that there are at least 30 amino acids total, which is consistent with applicant's remarks (*see above*), while the claim indicates that it could also require 90 amino acids minimum. It is unclear in the claim whether Applicant is claiming that each A, A′ and A′′ comprises 3 to 30 amino acids.

Claim 1 recites, "effective amount", which although defined in the specification, is unclear and indefinite, as the definition does not define what an effective amount is for a specific condition, reciting an equally indefinite definition, "An effective amount refers to the amount of [an RSPP] which is added to a personal care composition to provide the composition with a desired characteristic or characteristics." (emphasis added). It is unclear what characteristic(s)

are being provided and how one would know the metes and bounds of 'effective amount'. Is the desired characteristic simply gellation or some specific biological benefit?

Claims 1 and 3 recite "about" and it is unclear what constitutes "about 3" amino acids. The specification does not set forth boundaries or define 'about', and unlike a percentage, temperature or pH which can vary by fractions (e.g. about 7 % which could include 7.2%), amino acids cannot be fractioned (is methyl 'about' one alanine?), and thus it is indefinite.

Claim 2 recites, "derivative from", which is confusing and indefinite, as it is unclear how far one could 'derive' any of the recited proteins and still be with the scope of the claims (e.g. would alanine be a derivative of mucin?).

Claim 2 further recites, "or a mixture thereof", and it is unclear what defines a 'mixture thereof' of units 'derived from' the various proteins. Is it a mixture of the derivatives, or a derivative of the mixtures? How would one know whether a specific composition was within the metes and bounds of the claim?

Claim 2 further recites, "comprises a repeating amino acid sequence unit...", however it is unclear and indefinite whether this recitation is further comprising or whether this recitation is defining each A, A′ and A′′.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 9, 12-14 and 31 remain rejected under 35 U.S.C. 102(b) as being anticipated by WOLFINBARGER (US PGPUB 2002/0147154 A1).

The claims are drawn to repeat sequence protein polymers.

Wolfinbarger teaches a cosmetic composition, comprising marine invertebrate type V telopeptide collagen (claim 1), where the collagen is present in an amount of from 0.001 wt % to 30 wt % (claim 4), 0.1 wt % to 10 wt % (claim 5), or 0.2 wt % to 5 wt % (claim 6).

Wolfinbarger teaches a cream rinse hair-conditioner with collagen gelatin solution at 0.2 w/w % (Example 10, page 9). The cream rinse comprises carriers and excipients, e.g., cetyl alcohol, dimethicone, xanthan gum, water, and stearic acid. (Example 10).

The instant specification states, "Specifically, there are more than six hundred repeating amino acid sequence units known to exist in biological systems. For example, well known proteins containing repeating amino acid sequence units include abductin, elastin, byssus, flagelliform silk, dragline silk, gluten high molecular weight (HMW) subunit, titin, fibronectin, leminin, and collagen. Individual repeating amino acid sequence units of particular interest include units found in silk-, elastin-, collagen-, abductin-, byssus-, gluten-, titin-. extensin-, and fibronectin-like proteins... Collagen-like proteins comprise a repeating sequence unit of G-X-X^1, wherein X comprises any amino acid, X^1 comprises any amino acid, often proline or hydroxy-proline (SEQ ID NO:20)."(page 4, *Specification*).

Thus, any collagen meets the limitations of these claims regardless of the source, as the specification does not indicate that only one specific type from one specific source is the collagen that has a specific sequence in any RSPP. Additionally, application of the composition comprising collagen would necessarily provide a benefit to the surface to which it was applied.

Furthermore, Applicant has not provided any evidence to prove the type V telopeptide collagen is not the same as what is instantly claimed, but rather argues that, "Wolfinbarger fails to disclose any repeat sequence protein polymers that would anticipate the formula recited"

(page 9). As the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Alternatively, particularly with regards to claim 1 limitations, A, A′ and A′′ can each be absent, as dependent claim 3 particularly indicates that one of x, x′ and x′′ is not zero, and each subunit 'comprises' amino acids in a non limiting way, any peptide would read upon the instant claims- regardless of the length, composition, or presence/absence of a repeat unit.

Claims 1-4, 8, 9 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by CRISSMAN (J. Crissman, et al. J. Control. Rel. (1998) 53, pages 105-117).

The instant claims are presented *supra*.

Crissman teaches various SELPs, referring to them as ProLastins (e.g. Table 2).

One example being:

ProLastin 47K
MDPVVLQRRDWENPGVTQLNRLAAHPPFASDPM
GAGSGAGAGS[(GVGVP)$_4$GKGVP(GVGVP)$_3$(GAGAGS)$_4$]$_{12}$(GVGVP)$_4$
GKGVP(GVGVP)$_3$(GAGAGS)$_2$GAGA MDPGRYQDLRSHHHHHH , where T is

MDP....GAGS, A and A′ are each GVGVP and A′′ is GAGAGS, n is 4, n′ is 3 and n′′ is 4, i is 12 and T′ is $(GVGVP)_4$...HHH.

Crissman teaches ProLastin solutions were prepared at 20% (w/w) in PBS and injected into guinea pigs subcutaneously or intradermally (*2.5*, page 109).

Crissman teaches that Pantarin ™, a protein biopharmaceutical, is mixed with ProLastin 47K (*2.4*, page 109) and was injected into guinea pigs subcutaneously or intradermally (*3.5*, page 115).

The composition of Crissman is a 'personal care composition' as it provides a benefit, such as beautifying or treating via reduction of tumors, for example, and is applied to the 'associated membranes' of skin, being intradermally or subcutaneously injected. Associated membranes is not defined, and thus the broadest reasonable interpretation includes the various layers of the skin. Please note, the instant claims or specification definition do not require that the composition be a topically applied composition.

Claims 1-4, 8, 9 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by CAPPELLO (WO 95/24478 A1).

The instant claims are presented *supra*.

Cappello teaches a protein polymer of at least 15 kD comprising at least two units each of VPGVG and GAGAGS (claim 1) and composition comprising the two peptides in various combinations and ratios (e.g. claims 2-4).

Cappello teaches a method of maintaining separated viable tissue together using a device comprising the composition of claim 1 or a homopolymer of GAGAGS (claim 13) and the device is a suture, pin, thread, gel or film (claim 14).

Cappello teaches various SELPs (Table 1, page 10), e.g. SELP 5 (SEQ ID NO:8) is $[(VPGVG)_{16}(GAGAGS)_8]_8$. Each subunit is either a silk-like or elastin-like protein.

Cappello teaches that SELP 5 (SEQ ID NO:8) sponges were soaked in saline or water (page 16, lines 24-25) and applied to pig dermal wounds (page 16, line 34- page 17, line 26).

Water and saline are pharmaceutically acceptable carriers or excipients, thus the soaked sponge meets the limitations of being a personal care composition, as it provides a benefit, namely wound healing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 8, 9, 12-15 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/845,936 (COLLIER, US 2004/0234609 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each for the following reasons.

The instant claims are drawn generally to compositions comprising a RSPP, e.g. SEQ ID NO:19. Please note, the instant claims do not preclude the presence, or require the absence, of additional elements, particularly in view of the 'open' language of the claims ('comprising').

Collier claims biomolecular conjugates comprising RSPP and at least one active agent (claim 1), where the formula of the RSPP is that of instant claim 1 (claim 3), specifically claiming SEQ ID NO:19 (claim 12). Collier teaches various concentrations and compositions, e.g. an emulsion of the biomolecular conjugate with excipients and/or carriers, e.g. water, (claim 22 and 24) and a personal care product comprising the compositions (claims 23 and 25).

Broadly interpreted, 'specifically adapted' includes the attachment, via conjugation, of an active ingredient.

Further, MPEP § 804 (II) states, "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure." (*emphasis added*). "Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970)."

In the instant case, in looking to the specification for support for the claims, the example provide for the use of SELP 47K (SEQ ID NO:19) in each composition, further providing support that the claimed compositions comprise SEQ ID NO:19.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 8, 9, 12-15 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 14-33 and 41-50 of copending Application No. 10/845,775 (MAZEAUD, US 2004/0228913 A1). Please note, this rejection is based upon the claim set of March 1, 2006.

Although the conflicting claims are not identical, they are not patentably distinct from each for the following reasons.

The instant claims are presented *supra.*

Mazeaud claims a system for providing controlled release delivery of an active agent comprising an RSSP and an active ingredient (claim 1) where the RSPP is that of instant claim 1 (claim 3), specifically being SEQ ID NO:19 (claim 12) and the composition in various emulsions comprising carriers/excipients, e.g. water (claims 27 and 28). Further, the claims are drawn to various personal care compositions (claim 29).

In looking to the specification for support for the claims, SEQ ID NO:19 is the specifically recited peptide used in the compositions.

Please note, although the preamble of the claims differ, the compositions claimed are of an overlapping, if not commensurate scope, and any asserted activity would necessarily be present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 8, 9, 12-15 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 14-28 of copending Application No. 10/939,036 (KUMAR, US 2005/0142094 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each for the following reasons.

The instant claims are presented *supra.*

Kumar claims personal care compositions comprising an RSPP and a carrier or excipient (claim 1), where the specific RSPP is SEQ ID NO:19 (claim 14). Kumar teaches various concentrations for the RSPP (claims 15-17) and a composition where it comprises additional elements, e.g. thickening agents, (claim 28 and 30).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Inventorship/Ownership

Claims 1-4, 8, 9, 12-15 and 31 are directed to an invention not patentably distinct from claims 1-37 of commonly assigned Application No. 10/845,936 (COLLIER, US 2004/0234609 A1), claims 1-12, 14-33 and 41-50 of commonly assigned Application No. 10/845,775 (MAZEAUD, US 2004/0228913 A1) or claims 1-12 and 14-28 of commonly assigned Application No. 10/939,036 (KUMAR, US 2005/0142094 A1), for the reasons set forth *supra.*

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Collier, Maeaud and Kumar, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Art Unit 1654

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600